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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,795	10/31/2003	Sabina Cauci	13581 US	1736

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EXAMINER	
GITOMER, RALPH J	
ART UNIT	PAPER NUMBER
1657	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,795	CAUCI, SABINA	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-28* is/are pending in the application.

4a) Of the above claim(s) *17-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The IDS received 8/2/06 and the amendment received 10/6/06 have been entered and claims 1-3, 5-16 are considered here.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The addition to the claims of the sample being "cervo-vaginal fluid" is new matter. The term is not found in the specification as originally filed and "cervo" is queried.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-8 of copending Application No. 10/470,690. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '690 also include antibodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-54 of copending Application No. 10/467,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because the three elements presently claimed together are claimed separately in different combinations in '357. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 10/6/06 have been fully considered but they are not persuasive.

Applicant argues that they disagree with the rejections but no reasons are given.

It is the examiner's position that the claims in '690 and '357 remain currently pending, hence the rejection is maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Soothill, Johnson, Lawrence, Cauci, Cauci, McGregor, and Briselden.

Soothill (WO 00/55354) entitled "A Diagnostic Test" teaches on page 4 a test for sialidase activity as an indicator of BV and therefor a predictor of the likelihood of preterm birth.

Johnson (WO 00/24753) entitled "Chromogenic Substrates of Sialidase and Methods of Making and Using the Same" teaches on page 2 first paragraph, measurement of sialidase level in vaginal samples could be used to diagnose bacterial vaginosis.

Lawrence (5,571,684) entitled "Assay for Proline Iminopeptidase and Other Hydrolytic Activities" teaches in column 2 first full paragraph, vaginal pH of women with BV or trich is above 4.5, whereas the normal vaginal pH is less than 4.5. In column 7 second full paragraph, the substrate detects peptidases where the substrate residue is proline. In column 12, line 61, vaginal fluid is tested.

Cauci (Am J Obstet Gynecol) entitled "Immunoglobulin A Response Against Gardnerella vaginalis Hemolysin and Sialidase Activity in BV" teaches in the abstract, there is a correlation between sialidase activity in vaginal fluids and bacterial vaginosis.

Cauci (J of Infect Diseases) entitled "Impairment of the Mucosal Immune System" teaches on page 1698, BV is associated with preterm delivery, chorioamniotis, amniotic fluid infections, postcesarean endometritis, salpingitis, and HIV infection. On page 1701 sialidase activity correlated with BV and to a lesser extent prolidase where no prolidase activity was detected in healthy women.

McGregor (Am J Obstet Gynecol) entitled "Bacterial Vaginosis is Associated With Prematurity and Vaginal Fluid Mucinase and Sialidase" teaches in the abstract preterm birth and other adverse pregnancy outcomes are linked with infection. Sialidiases from BV are associated with vaginal microorganisms and intrauterine infection and preterm birth.

Briselden (J of Clinical Micro) entitled "Sialidases (Neuraminidases) in BV and BV Associated Microflora" teaches in the abstract, BV is associated with prematurity and upper genital tract infection. Elevated levels of sialidase activity is highly associated with BV.

The claims may differ from the above references in that they recite specific levels of sialidase and/or prolidase indicate some odds ratio value or score. Some dependent claims include a pH range determination and/or score.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to select a particular population of women at risk for pathologies by determining sialidase and/or prolidase because each of the above references teaches the same method for determining the risk of the same pathologies as claimed. Regarding the selection of some odds ratio being calculated from some level of detected sialidase and/or prolidase, no novelty is seen in such selection because each of the references show data, usually presented as a curve, where at some cutoff some degree of correlation between enzyme levels detected and pathology may be inferred. This is standard practice in clinical diagnosis. Regarding determining pH level of vaginal fluid as claimed, it is known and taught by some of the above references such as Lawrence that normal vaginal pH is below 4.5 and ranges above 4.5 are associated with BV and other pathologies.

Applicant's arguments filed 10/6/06 have been fully considered but they are not persuasive.

Applicant argues that the invention provides an objective value of the risk which is independent from detecting BV. McGregor determines mucinase and sialidase after treatment and does not quantify the risk. Briselden determines sialidase in women with and without BV, not the risk of other pathologies. He merely suggests there may be a connection between sialidase and risk of preterm labor or invasion of the amniotic cavity. Soothill, Lawrence and Johnson do not determine risk of pathologies related to the presence of bacteria. Cauci (Am J Obstet Gynecol) and (J of Infect Dis) do not study pregnant women

It is the examiner's position that the present claims select some value based on the activity of sialidase and/or prolidase as correlated to any obstetric or gynecologic pathology risk. Selecting any degree of risk would be encompassed by each of the above references which also teach some correlation between sialidase and/or prolidase activity and disease. Note that BV is a gynecologic pathology. Regarding Cauci, most claims do not require the subject to be pregnant and claim 10 requires that the woman is not pregnant.

A reading of the specification reveals no specific point of novelty. Regarding the presently claimed cutoff values regarding odds ratios, no patentability is seen in claiming some particular point on a curve. No results are claimed for such cutoff values.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to risk of developing obstetric or gynecologic pathologies in general. Claim 5 lists a number of pathologies including various sites of infection, STD's in general, and malignancies. It is not seen how the present invention could predict the risk of all such maladies. For example, does the invention predict the risk of a Nabothian cyst or ovarian carcinoma?

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative fluids claimed.

2. Amount of direction or guidance presented is insufficient to predict which fluids encompassed by the claims would work.

3. Presence of working examples are only for a single specific fluid and extension to other fluids has not been specifically taught or suggested.

4. The nature of the invention is complex and unpredictable.

5. State of the prior art indicates that most related fluids are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of fluids.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Applicant's arguments filed 10/6/06 have been fully considered but they are not persuasive.

Applicant argues that one of skill could practice the invention.

It is the examiner's position that the rejection is based on the specification as originally filed does not enable one to select the risk of developing any and all obstetric or gynecologic pathologies.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Independent claims should begin with an indefinite article, dependent claims should begin with a definite article. There are many instances of lack of antecedent basis in the claims, for example in claim 1(a) "the levels", in claim 1(b) "the pH value". Method claim 1 is incomplete where the preamble is not performed; a correlating step may be considered. In claim 1(c) the concentration of methoxyphenol does not appear related to the other steps and no determination of methoxyphenol is seen. In claim 2 the pH of what is not set forth. Claim 3 is not understood regarding "the a) phase". In all occurrences, "preferably" renders the claims indefinite as to what may be intended. In claim 12 the possessives of "weeks'" is queried. In claim 28 the method steps must be properly recited as gerunds. In claim 28(a) how it is evaluated for what is not seen. Claim 28(b) is not understood in context. In claim 28(d)(i) "body fluid samples" lacks antecedent basis. Claim 28 is an incomplete method claim which does not perform the function of the preamble.

This application contains claims 17-27 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ralph Gitomer
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Art Unit 1657